

In re: BEAUDRY et al.
US\$N: 10/818,079
Filed: April 1, 2004
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I. Remarks

Claims 1-29 are pending in the subject application and are subject to a restriction requirement.

II. Requirement for restriction under 35 U.S.C. 121

The Office has required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

- I. Claims 1-11 and 28, drawn to nucleic acids, classified in Class 536; subclass 23.5.
- II. Claim 12, drawn to proteins, classified in Class 530; subclass 350.
- III. Claim 13, drawn to antibodies, classified in Class 530, subclass 387.
- IV. Claims 14-18, drawn to methods of diagnosing lung cancer by detecting a polynucleotide, classified in Class 435, subclass 6.
- V. Claims 19 and 20, drawn to a method for detecting lung cancer by detecting a compound that binds to a gene, classified in Class 435, subclass 6.
- VI. Claims 21 and 22, drawn to methods for detecting lung cancer by identifying an agent that binds to a protein, classified in Class 435, subclass 7.1.
- VII. Claim 23, drawn to a computer system with data for the polynucleotide of SEQ ID NO: 1-40, classified in Class 702, subclass 19.
- VIII. Claim 24, drawn to a method of detecting lung cancer using a database classified in Class 702, subclass 19.
- IX. Claim 25, drawn to a method of screening databases, classified in Class 702, subclass 19.
- X. Claims 26 and 27, drawn to a method of screening for therapeutic agents, classified in Class 435, subclass 6.
- XI. Claim 29, drawn to a transgenic animal, classified in Class 800, subclass 13.

Further, if Groups I-IV and VI-XI are elected, the Office has required the election of one sequence from the group consisting of SEQ ID NOs: 1-40, or one combination thereof, or one protein encoded by the sequence of SEQ ID NO: 1-40 or one combination thereof, or one antibody directed to a polypeptide encoded by one of SEQ ID NO: 1-40, or one combination thereof, or one antibody directed to a polypeptide encoded by one of SEQ ID NO: 1-40, or combination thereof.

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If Groups V is elected, the Office has required the election of a single gene product selected from the group of gene products set forth in claim 19.

III. Provisional election with traverse required under 37 C.F.R. §1.143

In compliance with 37 C.F.R. §1.143, Applicants elect Group VI, drawn to methods of diagnosing lung cancer by detecting a polynucleotide, classified in Class 435, subclass 6, and elect SEQ ID NO: 1, with traverse for the reasons stated below.

IV. Request for reconsideration of the Restriction Requirement under 37 C.F.R. 1.143

Applicant respectfully requests a reconsideration and modification of this restriction requirement. Applicant asserts that the search of more than one nucleotide sequence in the instant claims does not comprise a serious burden to the Office. Additionally, even though the Office has established that a search of one polynucleotide sequence is not coextensive with another, the Office has failed to set forth reasons establishing why the examination of more than one nucleotide sequence in the instant claims constitutes an undue burden.

The Office has recently instituted a policy directed to improving restriction practice within TC 1600 as stated by the recent publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit.

There are two criteria for a proper requirement for restriction between patentably distinct inventions (MPEP 803). First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner in order to merit restriction. In the absence of a serious burden, the Examiner must examine the subject application on the merits even if it includes claims to distinct inventions. Although the Office has established that the instantly claimed polynucleotide comprise distinct inventions, it has failed to set forth specific reasons that establish why the examination of the elected claims constitutes a serious burden. Applicant asserts that the search of up to 10 polynucleotide sequences does not comprise such a serious burden.

First, the Office operates a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes (MPEP § 803.04). This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limits

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on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the instant polynucleotides) are considered reasonable to search. Therefore, it appears that the Office readily recognizes that a search of as many as 10 sequences constitutes a reasonable search and examination burden. Applicant points to the pertinent policy behind this decision in § 803.04:

"Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

Applicant asserts that it is reasonable to apply this policy to the search of the instant claims. Accordingly, Applicant respectfully requests that the current restriction requirement, under which Applicant would be required to prosecute numerous separate patent applications at considerable cost, be modified or vacated to allow for at least the eight nucleotide sequences currently present in the instant claims to be searched and examined together.

If this requirement is not modified or vacated and is made final by the Examiner, Applicant further reserves the right to petition from requirement for restriction under 37 C.F.R. §1.144.

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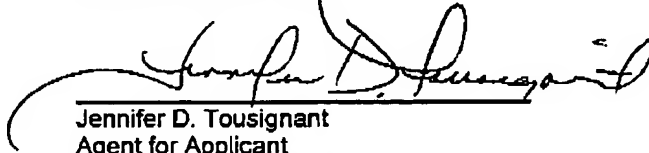
V. Conclusion:

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

Date

8/14/06



Jennifer D. Tousignant
Agent for Applicant
Registration No. 54,498
Telephone: (508) 270-2499
Facsimile: (508) 872-5415

GENZYME CORPORATION
15 Pleasant Street Connector
P.O. Box 9322
Framingham, Massachusetts 01701-9322